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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,879

08/10/2005

Finn Larsen

20747/260

2058

7590

05/04/2006

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EXAMINER

EBRAHIM, NABILA G

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/527,879	LARSEN, FINN	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-27 and 29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/16/05, 8/30/05</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt of Information Disclosure Statements filed 3/16/05, and 8/30/05 is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 15-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aiache et al. US 6210711 (hereinafter Aiache) in view of Cort et al. US 4237119 (hereinafter Cort).

Aiache teaches effervescent microspheres (title) microspheres containing an acid substance, a basic substance, and a water-soluble isolating agent which, when it dissolves in water, after almost instant effervescence, brings about a homogeneous dispersion of active principal(s) which is present in the acid and basic substances (abstract). The water-soluble isolating agent whose dissolution in water leads, after almost immediate effervescence, to a solution or a homogeneous dispersion of active principle (col. 2, lines 27-31). The water-soluble isolating agent is in the form of a thin film separating the acidic and alkaline substances (col. 2, lines 38-40). Each microsphere has a three-layer structure: a layer of acidic substance and a layer of alkaline substance separated by a layer of water-soluble isolating agent (col. 2, lines 38-

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43). Aiache disclosed that the pharmaceutical form of the composition may comprise tablets or powder and may comprise excipients (col. 1, lines 20-22).

Aiache also discloses a method for preparing the microspheres by rotational granulation on a fluid air-bed (abstract). The acidic and alkaline powders can also contain diluents, flavorings and sweeteners (col. 4, lines 56-59). With regard to claims 11, 12, 19, and 25, which recite the presence of the active principle inside or outside the microsphere, Aiache teaches that the composition includes a matrix in which the active principle is placed (col. 1, lines 12, and 13), or the active principle may be mixed with the acidic and basic substances, and the adjuvants are mixed together in a fluidized air-bed (col. 1, lines 44-48).

Aiache is deficient in disclosing oxytocin as an active principle, its dosage and uses.

Cort teaches a long-acting structural analog of oxytocin to safely induce labor in mammals (abstract), and facilitating milk production in dairy animals (col. 3, line 63). Cort explains in general that oxytocin is given in continuous infusion at 1 ml/min of a solution of 20 IU/l.—which represents a rate of about 40 ng or pmol/min—in 5% glucose, but constant monitoring of uterine contractions and fetal heartbeat are required to prevent tetany and fetal damage (col. 1, lines 45-55). In addition Cort teaches that by using his composition the preferred range of dosage is from about 10 ng to about 100 µg. per Kg. of body weight. A more preferred range is from about 1 µg to about 10 µg per Kg (col. 4, lines 65-68).

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Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to use the multilayered effervescent disclosed by Aiache and expand it with the knowledge taught by Cort to assist inducing labor and facilitate lactation, the motive would be that Aiache made his invention available to many drugs that can get use the general composition of the multilayer effervescent composition he disclosed and also the motivation would be according to the process for manufacturing microspheres, whether they are two-layer or three-layer microspheres, the powder of alkaline nature, one or more active principles if the latter have alkaline properties; whereas the powder of acidic nature may contain one or more active principles if the latter have acidic properties (col. 4, lines 43-55). The expected result would be an effervescent powder or tablet that can be used to assist inducing labor and facilitate lactation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

4/19/06


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER